IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Brian A. Rosenfeld, M.D. and Michael Breslow, M.D.

Serial No.:	09/443,072	Group Art Unit:	2167
Filed:	11/18/99	Examiner:	Harle, J.

For: SYSTEM AND METHOD FOR PROVIDING CONTINUOUS, EXPERT NETWORK CRITICAL CARE SERVICES FROM A REMOTE LOCATION(S)

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AFFIDAVIT BY DR. GENE BURKE

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I, Dr. Gene Burke, residing in Virginia Beach, Virginia, state as follows:

1. I obtained my M.D. degree in Medicine in 1975 from University of Virginia.

2. My experience includes 22 years in Intensive Care Medicine at Sentara Norfolk General Hospital.

3. My Curriculum Vitae is attached to provide further information regarding my background and qualifications that allow me to make the statements contained herein.

4. I have read and reviewed Patent Application Serial No.: 09/443,072 and the attached amended claim set.

5. I have read and reviewed the attached article "Intensive care unit telemedicine: Alternate paradigm for providing continuous care" from *Critical Care Medicine* 2000 Vol. 28, No. 12 by Rosenfeld et al.(the "Rosenfeld Study") describing the clinical study for which Dr. Rosenfeld was the Principal Investigator. I am familiar with the procedures described in this paper.

6. I believe the claimed invention is materially different from the Rosenfeld Study for at least the following reasons:

   - The claimed invention provides centralized monitoring of a plurality of geographically disparate ICUs. In contrast the Rosenfeld Study monitored only one single specialty 10-bed ICU. It is the capability of the claimed invention to allow a physician-lead team made up of intensive care specialists, critical care nurses and clerical support personnel (care team) to care for patients in multiple ICU's in disparate

geographic locations either within a building or in different buildings simultaneously that creates new efficiencies and offers the potential to change the care paradigm for ICU patients. Thus the expertise of the entire care team is leveraged over many ICU patients.

- In contrast to the Rosenfeld Study where a single intensivist monitored faxed information, or had to initiate communication to view a bedside monitor over a personal computer, the claimed invention uses a computerized patient care management system that feeds key clinical information on multiple ICU patients simultaneously to the remote monitoring care team. The claimed invention includes imbedded decision support algorithms that further assist the care team in the continuous monitoring of large numbers of ICU patients. The claimed invention analyzes simultaneously all incoming patient physiologic monitored and laboratory data and provides visual alarms for the care team and alerts the care team to detrimental trends in patient vital signs and/or laboratory values of which the care team might not be aware in as timely a fashion. These features of the claimed invention allow a single physician-led team to care for patients in multiple, geographically disparate sites simultaneously. These features are totally lacking from the Rosenfeld Study and are not suggested by the study in any way.

- The claimed invention provides for 24-hour dedicated monitoring/management by a care team. The care team provides this service from a dedicated monitoring facility comprising equipment and decision support algorithms developed explicitly for this purpose. The claimed invention provides for automated warnings relating to vital signs and trends in vital signs, provides assessment of those trends for the intensivist, and makes recommendations for intervention available for consideration by the intensivist. The care team has no other care responsibilities during the time it is monitoring/managing the multiple geographically disparate ICU(s). The attention of the care team is devoted to the ICU patients and only the ICU patients.

- In contrast to the present invention, the Rosenfeld Study provided only 4-5 hours of ad hoc monitoring by a single intensivist from the intensivist's home (i.e. no continuous monitoring, no support personnel, and no dedicated facility. Further, the intensivist monitoring was not triggered in any automated way by any form of decision support algorithms but was conducted periodically by the intensivist as he deemed fit and time permitted. The intensivist was solely responsible for analyzing the data, deducing trends in the patent's vital signs, assessing the meaning of the trends, and deciding on the corrective action to be taken.

7. I believe that remote, 24-hour intensivist-lead care team monitoring of ICU patients in multiple geographically disparate locations is not taught by the Rosenfeld Study nor would one of skill in the art make the required changes to the equipment and procedures of the Rosenfeld Study to arrive at the present invention for at least the following reasons:

- Remote monitoring and direct intervention of ICU patients is contrary to prior accepted practice where physicians are physically present in the ICU.

- The generally accepted medical monitoring paradigm in ICU's with intensivists on-staff is for the intensivists to conduct rounds with the staff, and for ICU nurses and other physicians to notify the intensivists of emergencies on an as-needed basis. The Rosenfeld Study subscribed to this generally accepted model of intensivist deployment in ICU's, daily rounds, periodic monitoring, and responding to requests for assistance from on-site personnel.

- The monitoring paradigm presently employed by hospitals is to provide most continuous direct monitoring of patients by lower-skilled bedside nurses. These personnel, with only bedside patient monitoring equipment and visual inspection, are relied on to make the decision to contact specialists, such as intensivists, for ICU patients.

- The invention described and claimed in Application Serial No.: 09/443,072 does not rely on the paradigm of direct monitoring by bedside personnel to make the decision when to contact the intensivist, but rather has the intensivist-lead care team provide continuous, 24-hour monitoring. The care team is capable of unilaterally entering the patient room for video and audio communication and is supported by decision support algorithms for automatically alerting the intensivist to detrimental trends in a patient's vital signs and facilitating the intensivist contacting the lower-skilled on-site personnel for intervention. Although the Rosenfeld Study included intensivist-initiated intervention, the lack of 24-hour continuous monitoring illustrates that the prior art monitoring paradigm was still considered valid by those in the Rosenfeld Study.

- The Rosenfeld Study disclosed nothing of the technological nature disclosed in the claimed invention. Indeed the only way the intensivist had contact with the ICU and could conduct a specific type of monitoring was for the intensivist to intermittently conduct specific a dial-up direct monitoring of the real-time bedside waveforms, request information by fax machine at the intensivist location, and to telephonically contact an ICU nurse and have equipment (such as a video monitor) physically moved to the desired patient location. None of this activity was in response to any system of automated notification to the intensivist.

- The technology tools that were developed in the current invention, such a smart alarms and trend analysis, instantly available video monitoring from permanent installations near each ICU bed, **the video monitoring being controlled selectively by the intensivist**, and data-linked command center were not available at the time of the original clinical study nor was their use suggested in any way.

- The initial clinical study never addressed the potential for a single monitoring site for monitoring multiple ICU's thereby leveraging the expertise of an intensivist over a number of ICU's in geographically disparate locations.

- The original trial technology suite could not have been used over multiple ICU's in different geographic locations.

- At the time the clinical study it was unprecedented to have an intensivist functioning in a dedicated monitoring capacity and NOT attending to other functions.

- During the clinical study, an intensivist was required to monitor on a 24-hour shift, which was physically and mentally far too demanding. In contrast, the system of the current invention allows for constant monitoring by an intensivist-lead care team functioning on a normal 6-12 hour shift thereby alleviating both the physical and mental stress associated with a 24-hour shift.

- The Rosenfeld study was not the same model as that used in the present invention's model. The functioning of the current system constitutes an entirely different manner of monitoring multiple, geographically disparate ICU's than the clinical study which monitored but a single ICU without the analytical support offered in the present invention system.

- **For a variety of licensing and clinical reasons, the clinical study was not a feasible model to use for a hospital. Using the clinical study as a model would require that the sickest patients be moved to a single ICU for intensivist monitoring and care, rather than having multiple ICU facilities serving this purpose as they normally would. This, in my opinion, is NOT something that any prudent hospital would do.**

- When compared to the original standard of care, that is, an on-call intensivist, the results of using the present invention are remarkable, resulting in far better outcomes for ICU patients and far earlier intervention in life-threatening trends.

8. I believe that providing either a computerized patient care management system or a set of decision support algorithms to a remote care team (or a combination thereof) is not taught by the Rosenfeld Study, and neither the paper nor the standard practices of the time would suggest such a modification for at least the following reasons:

    - The use of computerized patient care management systems at the time of the invention was limited in major hospitals to the recording of patient data to be reviewed by a physician later in time, and those isolated systems that sound an alarm when an extreme condition in a patient's vital signs is reached (i.e. cardiac arrest). Further, computerized decision support algorithms in the medical community were not available.

    - When computerized patient care management systems are deployed by hospitals, they are provided at the bedside or ICU nursing stations. They are not provided remotely to a physician. Instead, physicians are contacted by a bedside nurse (via a "pager") to inform them that a problem has developed.

    - Since the accepted wisdom of the medical community is to deploy patient care management systems and/or paper-based decision support for lower-skilled medical care

givers on-site, there would be no reason to deploy these systems at a remote site for a care giver having the higher-skills of an intensivist.

9. The Rosenfeld Study evaluated the potential of "currently available technology" to "extend the effective reach of intensivists," but failed to disclose or suggest any of the additional technology of the presently claimed invention, such as (i) intensivist access to patient care management systems and/or decision support algorithms, that are required to effectively scale the monitoring to a greater number of patients and (ii) central command center monitoring that is required to effect a viable remote ICU monitoring model, (iii) monitoring of a plurality of geographically disparate healthcare locations/ICUs from a single remote command center, (iv) the use of a care team to enable monitoring and intervention on multiple patients in geographically different locations and (v) a data server/data warehouse for storing and analyzing data.

Date: 11/07/02

Gene Burke, M.D.
Title: ASST MEDICAL DIRECTOR
Affiliation: SENTARA MEDICAL GROUP

WITNESS MY HAND and seal this 7th day of NOVEMBER, 2002.

Patricia Lynn May
Type Name of Notary

STATE OF VIRGINIA)
CITY) ss:
~~COUNTY~~ OF NORFOLK)

On this 7th day of NOVEMBER, 2002 personally appeared before me **Dr. Gene Burke** to me known, and known by me to be the same person described in and who executed the foregoing instrument, and acknowledged that he executed the same, of his own free will and for the purposes set forth.

Patricia L May
Notary Public

My Commission Expires: 6/30/04

Notarial Seal
Commonwealth of Virginia Notary Public Seal
My Commission Expires June 30, 2004
PATRICIA L. MAY